

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

FERRING PHARMACEUTICALS INC. and)
REBIOTIX INC.,)

Plaintiffs,)

v.)

FINCH THERAPEUTICS GROUP, INC.,)
FINCH THERAPEUTICS, INC., and FINCH)
THERAPEUTICS HOLDINGS, LLC,)

Defendants.)

C. A. No. 21-1694-JLH

FINCH THERAPEUTICS GROUP, INC.,)
FINCH THERAPEUTICS, INC., FINCH)
THERAPEUTICS HOLDINGS, LLC, and)
THE REGENTS OF THE UNIVERSITY OF)
MINNESOTA,)

Counterclaim Plaintiffs/Reply)
Defendants,)

v.)

FERRING PHARMACEUTICALS INC. and)
REBIOTIX INC.,)

Counterclaim Defendants/Reply Plaintiffs.)

ORDER

At Wilmington this 30th day of July, 2024, for the reasons extensively discussed at the hearing on July 23, 2024, IT IS HEREBY ORDERED that the following pending motions are resolved as follows:

1. Ferring's motion for summary judgment of no copying and no willful infringement (D.I. 256) is DENIED. Ferring's motion for summary judgment that certain asserted claims are indefinite under 35 U.S.C. § 112 because they contain an improper Markush group (D.I. 256) is

DENIED. Ferring's motion for summary judgment of invalidity under § 112 due to lack of written description support for the percent change and Markush group limitations (D.I. 256) is DENIED. Ferring's motion for summary judgment of invalidity under § 112 due to lack of written description support for the extract terms (D.I. 256) is DENIED; it is also DENIED to the extent the motion asks the Court to reconstrue the extract terms. Ferring's motion for summary judgment of non-infringement because REBYOTA is not FDA-approved for treating CDI (D.I. 256) is DENIED. Ferring's motion for summary judgment of invalidity under § 112 because the term substantially entire microbiota is indefinite (D.I. 256) is DISMISSED as moot. Ferring's motion for summary judgment that the Borody patents are unpatentable under 35 U.S.C. § 101 (D.I. 256) is DENIED. The parties should consult the transcript of the hearing for a full understanding of these rulings.

2. Ferring's motion for summary judgment that Finch cannot assert the doctrine of equivalents with respect to the particle size limitations and of no literal infringement of those limitations (D.I. 256) is GRANTED-IN-PART and DENIED-IN-PART. To the extent the motion seeks summary judgment of no literal infringement of the particle size limitations, it is denied. To the extent it seeks summary judgment of no infringement under the doctrine of equivalents on the basis that Finch's theory is barred by the principle of claim vitiation or that Finch's expert applies an improper doctrine of equivalents analysis, it is denied. The parties should consult the transcript of the hearing for a full understanding of these rulings. To the extent Ferring seeks summary judgment that prosecution history estoppel bars application of the doctrine of equivalents, Ferring's request is granted for the "no particle having a size of greater than 0.5 mm" limitation and denied for the "capable of passing through a 0.5 mm sieve" limitation. The parties' briefing on this issue was sparse. (D.I. 258 at 17–19; D.I. 281 at 17–20; D.I. 295 at 10–11.) The Court has reviewed the prosecution histories of U.S. Patent Nos. 10,251,914 (the "'914 patent"), 10,286,012 (the "'012

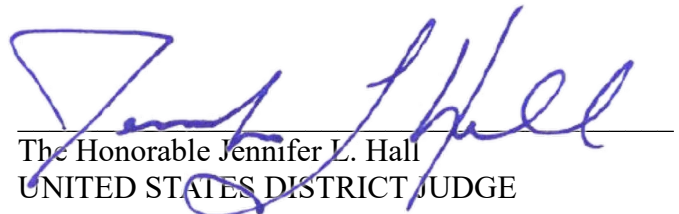
patent”), and their ancestor patents. As for the “no particle having a size of greater than 0.5 mm” limitation, which appears in asserted claims 18 and 23 of the ’914 patent and asserted claims 7, 9, and 12 of the ’012 patent, Finch acknowledged at the hearing that the claim amendments that added that limitation to the asserted claims were made for reasons substantially relating to patentability and thus give rise to the *Festo* presumption. (Tr. 43.) Finch nevertheless argues that the presumption is rebutted under the “tangential” exception. I disagree. That the amendments in question also added other limitations does not preclude the application of prosecution history estoppel; nor can I say (on this prosecution history record) that Finch’s claim of equivalence of particle sizes greater than 0.5 mm (measured in accordance with the Court’s claim construction) have only a peripheral relation to the reason for amending the claims to require “no particle having a size greater than 0.5 mm.” As for the limitation “wherein said fecal extract or preparation is capable of passing through a 0.5 mm sieve,” which appears in claim 7 of the ’914 patent, I agree with Finch that the record does not demonstrate that the limitation was added by amendment for reasons relating to patentability.¹

3. Ferring’s *Daubert* motion to exclude certain opinions of Mr. Malackowski (D.I. 257) is DENIED. The Court has reviewed the submitted portions of Mr. Malackowski’s reports and testimony and has considered the parties’ arguments and the cited cases. Ferring takes issue with Mr. Malackowski’s opinion about the structure of the hypothetical license—which includes an upfront fee plus ongoing payments—but his report sufficiently explains the basis for his opinion and the cited cases do not say that such a structure is impermissible. Ferring contends that Mr.

¹ The parties were advised at the July 23, 2024 hearing to meet and confer about whether the verdict form should nevertheless include special interrogatories directed to infringement under the doctrine of equivalents (in case the Court is later determined to have erred with respect to its application of the doctrine of prosecution history estoppel).

Malackowski's analysis is not reliable because the licenses he relies on are not sufficiently comparable; however, he assessed the comparability of the licenses and Ferring's critiques are fact issues best addressed by cross-examination. Ferring contends that Mr. Malackowski "errs" in asserting that the hypothetical license would be exclusive; however, Ferring acknowledged at oral argument that a hypothetical license can be an exclusive license. (Tr. 59–62.) Whether the parties would have negotiated such a license is a factual issue best addressed by cross-examination and not exclusion. Ferring argues that the 30% running royalty "lacks reliable support" but Mr. Malackowski explained how he came up with it, and Ferring's disagreement with his apportionment methodology is a matter for cross-examination, not exclusion.

4. Finch's motion for summary judgment of no equitable estoppel (D.I. 259) is DENIED. Finch's *Daubert* motion seeking to exclude Mr. Karst's opinions (D.I. 261) is DENIED. The parties should consult the transcript of the hearing for a full understanding of these rulings.



The Honorable Jennifer L. Hall
UNITED STATES DISTRICT JUDGE